R E M A R K S

This paper is responsive to an Official Action in this case that issued on April 8, 2008. In that Action, the Examiner rejected all pending claims (claims 1, 4-7, 13-19, 21-25, 28, and 33-40).

Responsive to the Action, claim 35 is hereby amended. Reconsideration is respectively requested in view of the following comments.

Claim Rejections under 35 USC §102

The Office rejected claims 35 and 38-40 under Section 102 as being anticipated by U.S. Pat. No. 6, 654,000 to Rosenberg.

Amended claim 35 recites an apparatus comprising:

> a pseudo skin;
> a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, including at least one mechanism for performing a ***non-invasive*** skin-interaction technique that is performed on said pseudo skin, wherein said plurality of mechanisms are disposed under said pseudo skin and are covered by said pseudo skin; and
> a housing, wherein said housing contains said plurality of mechanisms.

Rosenberg does not disclose what is recited in claim 35. In particular, Rosenberg does not disclose a "plurality of mechanisms with which a user interacts for simulation a vascular-access procedure, including at least one mechanism for performing a non-invasive skin-interaction technique that is performed on the pseudo skin."

Although it is clear that the phrase "skin interaction techniques," as used in applicant's specification, refers to non-invasive (non-penetrating) techniques, the Office has chosen to read that phrase more broadly. In fact, the Office considers the action of penetrating the skin as a "skin interaction technique." Rather than argue the point, applicant has amended claim 35 to clarify that the what is being referenced is a "non-invasive" skin interaction technique.

Since Rosenberg does not disclose a mechanism for performing a non-invasive skin-interaction technique, the Section 102 rejection of amended claim 35 over Rosenberg should be withdrawn. The Section 102 rejections of claims 38-40, which are dependent on claim 35, should be withdrawn as well.

Claim Rejections under 35 USC §103

A. Claims 1, 4, and 5

The Office rejected claims 1, 4 and 5 under Section 103 as being obvious over Rosenberg in view of U.S. Pub. Pat. App. 2003/0031993 to Pugh.

Claim 1 recites an apparatus comprising:

> pseudo skin;
>
> a receiver, wherein said receiver receives an end effector through an insertion region in said pseudo skin; and
>
> a first device for performing a first skin-interaction technique ***that is used in conjunction with*** a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein:
>
> (a) said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin; and
>
> (b) said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.

The Office admits that Rosenberg doesn't disclose skin interaction techniques such as palpation and occlusion, but alleges that Pugh does teach such techniques. The Office further states that limitation regarding the relative positions of the insertion region, the skin interaction region, and the user are met. The Office concluded that it would have been obvious to combine these two references to impart the ability, to Rosenberg, "to check for organs that on the organ surface or on the skin."

Claim 1 recites a limitation of "a first device for performing a first skin-interaction technique *that is used in conjunction with* a simulated vascular-access procedure." This is a rather specific limitation that narrows the "first skin-interaction technique" to palpating for a vein, occluding a vein, or stretching the skin. A practitioner does NOT palpate an organ "in conjunction with" a simulated vascular-access procedure. The recited "first device" must be a device that enables a user to practice palpating a vein, occluding a vein, or stretching

the skin. There is no disclosure or suggestion in Rosenberg or Pugh to practice any of these techniques, nor of a device that would enable a user to do so.

It is further noted that the usefulness of a simulator, such as applicant's claimed vascular access simulation system, is very dependent upon ergonomic considerations and the extent to which the simulator mimics the experience of conducting the actual procedure that is being simulated. As noted in the specification at paragraphs [0006]+, prior-art simulators did a generally poor job in simulating actual conditions, as a consequence of poor ergonomics and other factors. One of the focuses of applicant's vascular-access simulation system, and this patent application in particular, are the ergonomic aspects of the simulator's design.

Claim 1 recites a limitation that the "insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus." The Office effectively ignores this limitation, stating that "One region would be closer to a user than another region, depending upon the location of the user with respect to the apparatus."

That's certainly true, but that's the point! When using applicant's device as intended, the relative positions of the user, the insertion region, and first skin interaction region will be correct vis-à-vis the actual procedure. See, for example, FIGs. 3 and 8. With the device oriented as shown in FIG. 8, the insertion region (334) is closer to the user than the first skin-interaction region (331) for practicing palpation or occlusion. This is the orientation that would be used if someone *were performing the actual procedure on a live patient*. There is no teaching in the cited art to arrange a simulator to this end.

Accordingly, the Section 103 rejection of claim 1 over the combination of Rosenberg and Pugh should be withdrawn.

Claims 4 and 5, which are dependent on claim 1, are likewise allowable over the combination of these references. Furthermore, the recitation of additional patentable features in the dependent claims provides a secondary basis for patentability. For example, claim 4 recites:

> The apparatus of claim 1 further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-

> interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin.

These references do not teach or suggest performing "a second device for performing a second skin-interaction technique on the pseudo skin."

And claim 5 recites:

> The apparatus of claim 4 wherein:
> said second skin-interaction technique comprises skin stretching; and
> said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin when said user is using said apparatus.

Claim 5 recites details of the second skin-interaction technique and further addresses the ergonomics thereof. The cited art does not disclose or suggest performing a "skin stretching" technique. Nor does the cited art provide any disclosure or suggestion that the region where the skin-stretch technique takes place is closer to a user than the region where the end effector is inserted.

B. Claims 6, 7, and 13-24

The Office rejected claims 6, 7, and 13-24 under Section 103 as being obvious over Rosenberg and Pugh and further in view of U.S. Pat. No. 6,470,302 to Cunningham *et al*.

Claims 6 and 7 are dependent upon claim 1. As already shown, claim 1 is allowable over the combination of Rosenberg and Pugh. Cunningham does not remedy the shortcomings of these references vis-à-vis claim 1. For example, Cunningham does not disclose or suggest having "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion…." Cunningham only discloses performing a skin stretch technique. As a consequence, claim 1, as well as claims 6 and 7 dependent thereon, are allowable over the combination of Rosenberg, Pugh, and Cunningham.

The recitation of additional patentable features in claims 6 and 7 provide an additional basis for patentability. For example, claim 6 recites "a housing, wherein: (a) said receiver and said first device are contained within said housing; and (b) said pseudo skin is substantially co-extensive with a surface of said housing."

None of the three references cited, either alone or in combination, show or suggest that the first device (the device that enables a user to practice palpation or occlusion) in the housing and the pseudo skin being substantially co-extensive with the surface of the housing.

Claims 13-24 are all ultimately dependent upon claim 1. As already shown, the combination of Rosenberg, Pugh, and Cunningham do not teach or suggest what is recited in claim 1. Therefore, all claims dependent on claim 1, including claims 13-24, are allowable. The recitation of additional patentable features in these dependent claims provides an additional basis for patentability.

C. Claims 25, 28 & 33

Claim 25 recites an apparatus comprising:

> a housing, wherein said housing has an opening in an uppermost surface thereof;
>
> pseudo skin, wherein said pseudo skin covers said opening;
>
> an end effector, wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure; and
>
> a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin, and wherein said plurality of mechanisms include:
>
> (a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin; and
>
> (b) a second mechanism for receiving said end effector.

The combination of Rosenberg and Cunningham does not disclose what is recited in claim 25.

Namely, and among other features, Rosenberg does not disclose:

(a) a housing having an opening in an uppermost surface thereof;
(b) a plurality of mechanisms … contained completely within the housing;
(c) a first mechanism for simulating a skin-stretch technique.

The Office states the Rosenberg discloses a housing. The Office alleges that the "body" of a patient would be the housing. The relevant subject matter is a simulator. It is not clear to applicant how any part of the human body could possibly be used to support a claim of obviousness for a simulator. The purpose of the simulator is to mimic the experience of

the some procedure —here, vascular access— performing the procedure on an actual patient. The Office can't point to a human body to supply a missing element of the claimed invention. The relevant prior art is a simulator, not a human body. The fact that the Office has to rely on an anatomical feature of a human being, as opposed to a feature of the prior-art apparatus, aptly demonstrates the deficiency of the prior art as an invalidating reference.

Cunningham does not disclose:

(a) pseudo skin that covers the opening of the housing;
(b) an end effector that is inserted through the pseudo skin;
(c) a plurality of mechanisms that:
    (i) are contained completely within the housing;
    (ii) covered by the pseudo skin;
    (iii) one of mechanisms is for simulating a skin stretch;
    (iv) a second mechanism is for receiving the end effector.

Cunningham does not insert an end effector through "pseudo skin." If there is anything in Cunningham that can be termed "pseudo skin," it is belt (108) of the skin traction mechanism depicted in FIG. 7 and appearing in FIG. 3. It is quite clear from FIG 3. that the end effector (the relevant portion of the catheter unit assembly 34) is NOT inserted through belt (108).

Cunningham discloses several "housings." For example, the case (32) depicted in FIG. 3 that contains some (but not all) of the mechanisms shown in FIG. 4 is appropriately described as a housing. Also, casing (127) depicted in FIG. 3, which contains Cunningham's version of a mechanism for simulating a skin stretch (shown in detail in FIG. 7), is appropriately described as a housing.

But claim 25 recites a number of limitations, all of which pertain to the SAME housing. That is, the pseudo skin that covers the opening of the housing, the mechanisms that are contained completely within that housing and covered by the pseudo skin, the mechanism for simulating skin stretch, and the mechanism for receiving the end effector are all contained in the same housing. Cunningham does not disclose this nor suggest it. Furthermore, it would not be possible to modify the apparatuses shown in either of the references to meet all of the limitations recited in claim 25.

For these reasons, claim 25 is allowable over the combination of Rosenberg and Cunningham. Claims 28 and 33 are dependent on claim 25 and, therefore, are believed to be allowable as well.

The recitation of additional patentable features in claims 28 and 33 provides a further basis for their patentability.

For example, claim 28 recites:

> The apparatus of claim 25 wherein said mechanisms includes a third mechanism for simulating at least one of a palpation or an occlusion technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin, and wherein said end effector is at least one of either a needle or a catheter.

Rosenberg mentions neither skin stretch, palpation, nor occlusion. Cunningham discloses only skin stretch. The Office, however, alleges that Cunningham, at col. 11, lines 47+ discloses palpation or occlusion. That is incorrect; the disclose at the cited location pertains strictly to skin stretch.

Claim 33 returns to the issue of ergonomics and claims a positional relationship between two of the devices that are responsible for conducting the skin interaction techniques. This is not even hinted at in the cited art.

D. Claim 34

The Office rejected claim 34 over the combination of Rosenberg, Cunningham, and Pugh. Claim 34 recites, in pertinent part, the apparatus of claim 28 wherein:

> a user interacts with said first mechanism at a first site on said pseudo skin;
> said user interacts with said second mechanism at a second site on said pseudo skin;
> said user interacts with said third mechanism at a third site on said pseudo skin; and locations of each of said first site, second site, and third site on said pseudo skin correspond to locations of said first mechanism, second mechanism, and third mechanism, respectively, within said housing.

Claim 34 is allowable based on its dependence on claim 25, since the combination of Rosenberg, Cunningham, and Pugh do not obviate that base claim.

Moreover, the limitations of claim 34 are not suggested by the cited art. In particular, the claimed "first mechanism" is for practicing the skin stretch, the "second mechanism" is for receiving the end effector, and the "third mechanism" is for practicing palpation or occlusion. Claim 34 requires that (1) the user interact with these mechanisms at sites that are located on the pseudo skin; (2) that the locations of interaction correspond with the relative locations of these mechanisms within the housing (beneath the skin).

Pugh discloses no such thing. The Office cites to FIGs. 14A-C, 15, and 16 as support for the allegation that a user may interact with a plurality of simulated organs (i.e., mechanisms) via a plurality of openings on the simulator. What is shown in these Figures is a representation of the actual procedure being performed. These Figures do not demonstrate the procedure being performed on a manikin. In fact, the disclosure explicitly states various manikins are used as a function of the exam being performed:

> In one embodiment, system **10** is used for teaching abdominal exams and manikin **14** is an anatomical model of the lower chest to mid thing. Other anatomical models are sued to teach different exams. (para. [0038])

Furthermore, the disclosure states that removable, interchangeable organs and surfaces can be used. This indicates that access to organs is at the same location. That is, no need for interchangeable organs if a user accesses organs at different locations, only if access is at the same location. (para. [0038])

In view of the foregoing, claim 34 is allowable over the cited art.

E. Claims 36-37

The Office rejected claims 36 and 37 over Rosenberg. These claims are dependent on claim 35, which, it is believed, has been demonstrated to be allowable over Rosenberg. As a consequence, claims 36 and 37 are likewise allowable.

Claims 36 and 37 pertain to the height of the housing. These claims specify the height as being five inches and four inches, respectively. The reason for this is that the housing should not overtly defeat the fiction that the simulator is representative of a person's arm. That is, closer the total experience of a user during a simulation is to an actual vascular access procedure, the more meaningful the experience. One challenge is how to place all

the mechanisms that are required into a housing that is basically no higher than a person's arm.

Conclusion

It is believed that claims 1, 4-7, 13-19, 21-25, 28, and 33-40 now presented for examination are in condition for allowance. A notice to that effect is solicited.

Respectfully,
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